



# Oregon

John A. Kitzhaber, MD, Governor

**Oregon Board of Pharmacy**  
800 NE Oregon Street, Suite 150  
Portland, OR 97232  
Phone: 971 / 673-0001  
Fax: 971 / 673-0002

E-mail: [pharmacy.board@state.or.us](mailto:pharmacy.board@state.or.us)  
Web: [www.pharmacy.state.or.us](http://www.pharmacy.state.or.us)

**To: Drug Distribution Agents, Manufacturers and Wholesalers**

**From: Oregon Board of Pharmacy**

**Date: August 28, 2014**

**Re: Drug Supply Chain Security Act**

**Please review the information highlighted below related to the Drug Supply Chain Security Act (DSCSA), Title II of the Drug Quality and Security Act.**

The Drug Supply Chain Security Act (DSCSA), Title II of the Drug Quality and Security Act was signed into law by the President on November 27, 2013. The US Food and Drug Administration is directed to establish an electronic, interoperable system to identify and trace certain prescription drugs distributed in the United States.

Components of the new law will be implemented in multiple phases over the next 10 years. The new regulations impact drug manufacturers, wholesale drug distributors, repackagers, and dispensers (primarily pharmacies). The system, often referred to as "Track and Trace", will facilitate the exchange of information at the individual package level about where a drug has been in the supply chain. In addition, the system will enhance the FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful.

Among the key provisions to be implemented over the next 10 years are the following requirements:

- **Product identification:** Manufacturers and repackagers to put a unique product identifier on certain prescription drug packages, for example, using a bar code that can be easily read electronically.
- **Product tracing:** Manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) in the drug supply chain to provide information about a drug and who handled it each time it is sold in the U.S. market.
- **Product verification:** Manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to be able to verify the product identifier on certain prescription drug packages.

- **Detection and response:** Manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) to quarantine and promptly investigate a drug that has been identified as *suspect*, meaning that it may be counterfeit, unapproved, or potentially dangerous.
- **Notification:** Manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) to establish systems and processes to notify FDA and other stakeholders, if an illegitimate drug is found.
- **Wholesaler licensing:** Wholesale drug distributors to report their licensing status and contact information to FDA. This information will then be made available in a public database.
- **Third-party logistics provider licensing:** Third-party logistic providers, those who provide storage and logistical operations related to drug distribution, to obtain appropriate licensure.

**Please note the following federal requirements:**

Beginning **November 27, 2014**, third-party logistics providers (3PLs), who provide storage and logistical operations related to drug distribution, must obtain licensure. 3PLs shall report their state licensing status and contact information to the FDA. This information will then be made available in a public database.

Beginning **January 1, 2015**, wholesale drug distributors shall report their state licensing status and contact information to the FDA. This information will then be made available in a public database.

Beginning no later than **January 1, 2015**, under section 582(b)(4)(B)(ii), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii) of the FD&C Act, a manufacturer, repackager, wholesale distributor, and dispenser who determines that a product in its possession or control is illegitimate, as defined in section 581 of the FD&C Act (21 U.S.C. 360eee), must notify the FDA and all immediate trading partners of that determination not later than 24 hours after the determination is made.

For questions about implementation processes please contact the FDA at: [drugtrackandtrace@fda.hhs.gov](mailto:drugtrackandtrace@fda.hhs.gov).

The Board of Pharmacy is continuing to work on drafting rule amendments to its Drug Distribution Agent, Manufacturer, and Wholesaler rules. Please continue to monitor the Board's website at: [www.pharmacy.state.or.us](http://www.pharmacy.state.or.us) and click on the "Laws and Rules" tab for rule changes.

For more information regarding Drug Supply Chain Security Act (DSCSA), Title II of the Drug Quality and Security Act please visit the U.S. Food and Drug Administration's website at: [www.fda.gov](http://www.fda.gov).